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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Amprolium and Bacitracin Methylene Disalicylate

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved, single-ingredient amprolium and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds used for the development of active immunity to coccidiosis, increased rate of weight gain, and improved feed efficiency in replacement chickens.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–1600.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–156 that provides for use of Amprol® (25 percent amprolium) and BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound bacitracin methylene disalicylate) Type A medicated articles to make combination Type C medicated feeds containing 36.3 to 113.5 grams per ton (g/ton) amprolium and 4 to 50 g/ton bacitracin methylene disalicylate for use in replacement chickens. The Type C medicated feeds are used for the development of active immunity to coccidiosis, increased rate of weight gain, and improved feed efficiency in replacement chickens.

The NADA is approved as of February 12, 2001, and 21 CFR 558.55 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.55 is amended in the table in paragraph (d)(2) by alphabetically adding an item under entry (i) to read as follows:

§ 558.55 Amprolium.

* * * * *

(d) * * *

(2) * * *

Amprolium in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 36.3 to 113.5 (0.004% to 0.0125%).				
*	*	*	*	*
	Bacitracin methylene disalicylate 4 to 50.	Replacement chickens; development of active immunity to coccidiosis, increased rate of weight gain, and improved feed efficiency.	Feed according to subtable in item (i); bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.	046573
*	*	*	*	*

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Dated: 4/9/01
April 9, 2001.

Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

[FR Doc. 01–????? Filed ??–??–01; 8:45 am]

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